

Application Number 10/773,121  
Responsive to Office Action mailed March 23, 2006

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings of claims in the application.

#### **Listing of Claims:**

Claim 1 (Currently Amended): A stimulation lead introducer comprising:  
an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section; and  
an elongated sheath defining a sheath lumen sized to accommodate the dilator or [[the]] a stimulation lead.

Claim 2 (Original): The stimulation lead introducer of claim 1, wherein the sheath has a substantially oblong cross-section.

Claim 3 (Original): The stimulation lead introducer of claim 1, wherein the sheath has a substantially oblong cross-section with a width of the cross-section of the sheath that is greater than approximately two times a height of the cross-section of the sheath.

Claim 4 (Original): The stimulation lead introducer of claim 1, wherein the dilator lumen has a substantially oblong cross-section.

Claim 5 (Original): The stimulation lead introducer of claim 1, wherein the sheath lumen has a substantially oblong cross-section.

Claim 6 (Original): The stimulation lead introducer of claim 1, wherein the sheath comprises a material that is substantially deformable.

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Claim 7 (Original): The stimulation lead introducer of claim 6, wherein the material is polyethylene.

Claim 8 (Original): The stimulation lead introducer of claim 1, wherein the dilator comprises a material that is substantially deformable.

Claim 9 (Original): The stimulation lead introducer of claim 8, wherein the material is polyethylene.

Claim 10 (Original): The stimulation lead introducer of claim 1, wherein the dilator is at least as long as the sheath.

Claim 11 (Original): The stimulation lead introducer of claim 1, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

Claim 12 (Original): The stimulation lead introducer of claim 1, wherein the substantially conical distal tip comprises a proximal opening having an oblong cross-section such that a width of the proximal opening is greater than a height of the proximal opening.

Claim 13 (Original): The stimulation lead introducer of claim 12, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

Claim 14 (Original): The stimulation lead introducer of claim 1, wherein the sheath includes radiopaque material that is viewable under fluoroscopic imaging.

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**Claim 15 (Original):** The stimulation lead introducer of claim 1, wherein the sheath lumen has a cross-section with a width of the cross-section of the sheath lumen that is greater than approximately two times a height of the cross-section of the sheath lumen.

**Claim 16 (Original):** A method for introducing a stimulation lead comprising:

inserting a stimulation lead introducer into an epidural region proximate a spine of a patient via a guidewire, wherein the introducer includes:

an elongated dilator defining a dilator lumen sized to advance over the guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or the stimulation lead;

withdrawing the dilator from the sheath; and

introducing a stimulation lead to a target site within the epidural region via the sheath.

**Claim 17 (Original):** The method of claim 16, further comprising:

inserting a needle with a stylet into the epidural region proximate a spine of a patient;

withdrawing the stylet from the needle;

inserting the guidewire into the needle such that a distal end of the guidewire extends to the target site within the epidural region;

withdrawing the needle;

inserting the stimulation lead introducer into the patient via the guidewire following withdrawal of the needle;

withdrawing the guidewire; and

introducing the stimulation lead via the sheath following withdrawal of the dilator and the guidewire.

**Claim 18 (Original):** The method of claim 17, further comprising withdrawing the sheath.

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**Claim 19 (Original):** The method of claim 17, further comprising activating the stimulation lead to stimulate a nerve.

**Claim 20 (Original):** The method of claim 17, further comprising attaching a syringe to the needle, prior to inserting the guidewire into the needle, and attempting to inject fluid into the epidural region via the syringe and the needle to evaluate a position of the needle.

**Claim 21 (Original):** The method of claim 17, further comprising using an imaging technique to visualize introduction of the stimulation lead.

**Claim 22 (Original):** The method of claim 21, wherein the imaging technique comprises fluoroscopic imaging.

**Claim 23 (Original):** The method of claim 17, wherein the needle is a Tuohy needle.

**Claim 24 (Original):** The method of claim 16, wherein the sheath has a substantially oblong cross-section.

**Claim 25 (Original):** The method of claim 16, wherein the sheath has a substantially oblong cross-section with a width of the cross-section of the sheath that is greater than approximately two times a height of the cross-section of the sheath.

**Claim 26 (Original):** The method of claim 16, wherein the dilator lumen has a substantially oblong cross-section.

**Claim 27 (Original):** The method of claim 16, wherein the sheath lumen has a substantially oblong cross-section.

**Claim 28 (Original):** The method of claim 16, wherein the sheath comprises a material that is substantially deformable.

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Claim 29 (Original): The method of claim 28, wherein the material is polyethylene.

Claim 30 (Original): The method of claim 16, wherein the dilator comprises a material that is substantially deformable.

Claim 31 (Original): The method of claim 30, wherein the material is polyethylene.

Claim 32 (Original): The method of claim 16, wherein the dilator is at least as long as the sheath.

Claim 33 (Original): The method of claim 16, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

Claim 34 (Original): The method of claim 16, wherein the substantially conical distal tip comprises a proximal opening having an oblong cross-section such that a width of the proximal opening is greater than a height of the proximal opening.

Claim 35 (Original): The method of claim 34, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

Claim 36 (Original): The method of claim 16, wherein the sheath includes radiopaque material that is viewable under fluoroscopic imaging.

Claim 37 (Original): The method of claim 16, wherein the sheath lumen has a cross-section with a width of the cross-section of the sheath lumen that is greater than approximately two times a height of the cross-section of the sheath lumen.

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**Claim 38 (Original):** A dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient, the dilator having a proximal end and a distal end, wherein the dilator defines a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section.

**Claim 39 (Original):** The dilator of claim 38, wherein the dilator is formed from a material that is substantially deformable.

**Claim 40 (Original):** The dilator of claim 39, wherein the material is polyethylene.

**Claim 41 (Original):** The dilator of claim 38, wherein the dilator lumen has a substantially oblong cross-section.

**Claim 42 (Original):** The dilator of claim 38, wherein the substantially conical distal tip comprises a proximal opening and a distal opening, the proximal opening having a substantially oblong cross-section and the distal opening having a substantially circular cross-section.

**Claim 43 (Original):** The dilator of claim 42, wherein the width of the proximal opening is greater than or equal to approximately three times the height of the proximal opening.

**Claim 44 (Previously Presented):** The stimulation lead introducer of claim 1, wherein a width of an outside of the sheath is within a range from approximately 5.21 millimeters to approximately 7.75 millimeters, and a height of the outside of the sheath is within a range from approximately 3.05 millimeters to approximately 3.56 millimeters.

**Claim 45 (Previously Presented):** The stimulation lead introducer of claim 1, wherein the dilator and the sheath are sized for insertion into an epidural region of a patient.

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**Claim 46 (Currently Amended):** A kit comprising:

a stimulation lead introducer, wherein the stimulation lead introducer includes:

an elongated dilator defining a dilator lumen sized to advance over a guidewire, the dilator having a substantially conical distal tip, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, and

an elongated sheath defining a sheath lumen sized to accommodate the dilator or [[the]] a stimulation lead; and

the stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode.

**Claim 47 (Previously Presented):** The kit of claim 46, wherein the distal end of the stimulation lead has a substantially rectangular cross-section.

**Claim 48 (Previously Presented):** The kit of claim 46, wherein the distal end of the stimulation lead is substantially paddle-shaped.

**Claim 49 (Previously Presented):** The kit of claim 46, wherein a width of an outside of the sheath is within a range from approximately 5.21 millimeters to approximately 7.75 millimeters, and a height of the outside of the sheath is within a range from approximately 3.05 millimeters to approximately 3.56 millimeters, and the distal end of the stimulation lead has a width within a range from approximately 3.81 millimeters to approximately 4.32 millimeters and a height within a range from approximately 1.02 millimeters to approximately 1.40 millimeters.

**Claim 50 (Previously Presented):** The kit of claim 46, wherein the dilator and the sheath are sized to enter an epidural region of a patient.